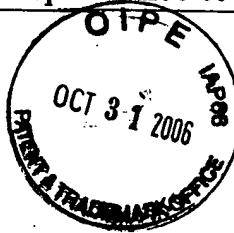


Please Direct All Correspondence to Customer Number 20995

Applicant : Fogel, Barry S.
App. No : 09/893,244
Filed : June 27, 2001
For : METHODS OF TREATING TARDIVE
DYSKINESIA AND OTHER
MOVEMENT DISORDERS
Examiner : Williams, Leonard M.
Art Unit : 1617



Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF BARRY S. FOGEL, M.D., UNDER 37 C.F.R. §1.132

I, Barry S. Fogel, M.D., declare and state:

1. I am the sole inventor of the above-referenced application.
2. I received my M.D. degree from the University of California, San Francisco in 1976. From 1976-1977, I was an Intern at Peter Bent Brigham Hospital, Harvard Medical School, Boston, Massachusetts. From 1977-1979, I was a Resident in Neurology, Harvard-Longwood Neurological Training Program. From 1979-1981, I was a Resident in Psychiatry, Stanford University Medical Center, Palo Alto, California. From 1981-1996, I was a faculty member at Brown University Medical School, Providence, Rhode Island (Full Professor 1992-1996). I am currently a Clinical Professor of Psychiatry at Harvard Medical School, with clinical privileges in Neurology and Psychiatry at the Brigham and Women's Hospital in Boston. I am Board Certified in Neurology and Psychiatry with Added Qualifications in Geriatric Psychiatry. I am the Co-founder and a Distinguished Fellow of the American Neuropsychiatric Association. I am the

editor of 10 textbooks and monographs, and author of over 125 articles and book chapters in neurology, psychiatry, geriatrics and long-term care, including *Neuropsychiatry: A Comprehensive Textbook* with Randolph Schiffer and Stephen Rao – one of the leading texts in the field. I am an internationally-recognized specialist in neuropsychiatry.

3. I have personally treated or consulted on the care of over 150 patients with tardive dyskinesia (TD).

4. I have attempted to treat patients suffering from movement disorders with magnesium alone. However, I observed, or the patients reported, little or no improvement in the disorder when magnesium alone was administered. This is consistent with anecdotal reports from colleagues in the field.

5. In one case, I administered magnesium oxide equivalent to 250 mg of elemental magnesium three times per day for several days, to a 46 year old man with a simple tic of the neck. No improvement in the frequency or the severity of the tic was observed. I did not administer magnesium alone to any of the patients described in any of the other reported case studies because I was convinced that magnesium alone would not have any beneficial therapeutic effect.

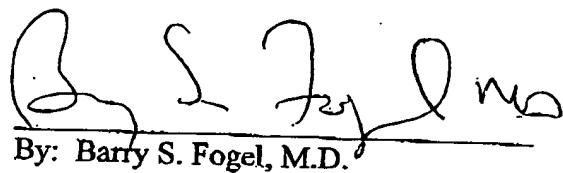
6. Case Report 5 in U.S. Patent Application No. 09/893,244 further describes the subsequent treatment of the 46 year old man with the simple tic movement disorder discussed in paragraph 5 above. The patient was initially treated with 666 mg acamprosate, three times daily. This resulted in significant reduction in frequency and severity of the tic. When chelated magnesium oxide, at a dosage equivalent to 300 mg elemental magnesium, was given three times daily in addition to the acamprosate, the usual tic-free period after each acamprosate dose increased from about 3 to about 5 hours. The ability of magnesium to further improve TD symptoms beyond that observed with acamprosate is also described in Case Studies 3, 4 and 5 in the specification.

7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

10/25/06

Dated



A handwritten signature in black ink, appearing to read "Barry S. Fogel, M.D."

By: Barry S. Fogel, M.D.

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